entity's official responsible for coordination of the FFD program an annual statistical summary of urinalysis testing, which may not include any personal identifying information. To avoid sending data from which it is likely that information about a donor's test result can be readily inferred, the laboratory may not send a summary report if the licensee or other entity has fewer than 10 specimen test results in a 1-year period. The summary report must include test results that were reported within the year period. The laboratory shall send the summary report to the licensee or other entity within 14 calendar days after the end of the 1-year period covered by the report. The statistics must be presented either for the cutoff levels specified in this part or for any more stringent cutoff levels that the licensee or other entity may specify. The HHS-certified laboratory shall make available quantitative results for all specimens tested when requested by the NRC, licensee, or other entity for whom the laboratory is performing drug-testing services. If the FFD program tests for additional drugs beyond those listed in §26.31(d), the summary must include drug test results for the additional drugs. The summary report must contain the following information:

(1) Total number of specimens received;

(2) Number of specimens reported as—

(i) Negative, and

(ii) Negative and dilute;

(3) Number of specimens reported as positive on confirmatory tests by drug or drug metabolite for which testing is conducted, including, but not limited to—

(i) Marijuana metabolite;

(ii) Cocaine metabolite;

(iii) Opiates (total);

(A) Codeine;

(B) Morphine; and

(C) 6-AM;

(iv) Phencyclidine;

(v) Amphetamines (total);

(A) Amphetamine; and

(B) Methamphetamine;

(4) Total number of specimens reported as adulterated;

(5) Total number of specimens reported as substituted;

(6) Total number of specimens reported as positive and dilute [including an indication as to whether the specimen was subject to the special analysis permitted in §26.163(a)(2)];

(7) Total number of specimens reported as invalid; and

(8) Number of specimens reported as rejected for testing and the reason for the rejection.

Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness

§26.181 Purpose.

This subpart contains requirements for determining whether a donor has violated the FFD policy and for making a determination of fitness.

§26.183 Medical review officer.

(a) *Qualifications.* The MRO shall be knowledgeable of this part and of the FFD policies of the licensees and other entities for whom the MRO provides services. The MRO shall be a physician holding either a Doctor of Medicine or Doctor of Osteopathy degree who is licensed to practice medicine by any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. By March 31, 2010, the MRO shall have passed an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of Federally mandated drug tests.

(b) *Relationships.* The MRO may be an employee of the licensee or other entity or a contractor. However, the MRO may not be an employee or agent of, or have any financial interest in, an HHS-certified laboratory or a contracted operator of a licensee testing facility for whom the MRO reviews drug test results. Additionally, the MRO may not derive any financial benefit by having the licensee or other entity use a specific drug testing laboratory or licensee testing facility operating contractor and may not have any agreement with such parties that may be

construed as a potential conflict of interest. Examples of relationships between laboratories and MROs that create conflicts of interest, or the appearance of such conflicts, include, but are not limited to—

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the licensee or other entity is to use, gives the licensee or other entity a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the licensee or other entity a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or

(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

(c) *Responsibilities.* The primary role of the MRO is to review and interpret positive, adulterated, substituted, invalid, and at the licensee's or other entity's discretion, dilute test results obtained through the licensee's or other entity's testing program and to identify any evidence of subversion of the testing process. The MRO is also responsible for identifying any issues associated with collecting and testing specimens, and for advising and assisting FFD program management in planning and overseeing the overall FFD program.

(1) In carrying out these responsibilities, the MRO shall examine alternate medical explanations for any positive, adulterated, substituted, invalid, or, at the licensee's or other entity's discretion, dilute test result. This action may include, but is not limited to, conducting a medical interview with the donor, reviewing the donor's medical history, or reviewing any other relevant biomedical factors. The MRO shall review all medical records that the donor may make available when a positive, adulterated, substituted, invalid, or dilute test result could have resulted from responsible use of legally prescribed medication, a documented condition or disease state, or the demonstrated physiology of the donor.

(2) The MRO may only consider the results of tests of specimens that are collected and processed under this part, including the results of testing split specimens, in making his or her determination, as long as those split specimens have been stored and tested under the procedures described in this part.

(d) *MRO staff.* Individuals who provide administrative support to the MRO may be employees of a licensee or other entity, employees of the MRO, or employees of an organization with whom a licensee or other entity contracts for MRO services. Employees of a licensee or other entity who serve MRO staff functions may also perform other duties for the licensee or other entity and need not be under the direction of the MRO while performing those other duties.

(1) Direction of MRO staff activities. MROs shall be directly responsible for all administrative, technical, and professional activities of individuals who are serving MRO staff functions while they are performing those functions, and those functions must be under the MRO's direction.

(i) The duties of MRO staff must be maintained independent from any other activity or interest of a licensee or other entity, in order to protect the integrity of the MRO function and donors' privacy.

(ii) An MRO's responsibilities for directing MRO staff must include, but are not limited to, ensuring that—

(A) The procedures being performed by MRO staff meet NRC regulations and HHS' and professional standards of practice;

(B) Records and other donor personal information are maintained confidential by MRO staff and are not released to other individuals or entities, except as permitted under this part;

(C) Data transmission is secure; and

(D) Drug test results are reported to the licensee's or other entity's designated reviewing official only as required by this part.

(iii) The MRO may not delegate any of his or her responsibilities for directing MRO staff to any other individual or entity, except another MRO.

(2) MRO staff responsibilities. MRO staff may perform routine administrative support functions, including receiving test results, reviewing negative test results, and scheduling interviews for the MRO.

(i) The staff under the direction of the MRO may receive, review, and report negative test results to the licensee's or other entity's designated representative.

(ii) The staff reviews of positive, adulterated, substituted, invalid, and, at the licensee's or other entity's discretion, dilute test results must be limited to reviewing the custody-and-control form to determine whether it contains any errors that may require corrective action and to ensure that it is consistent with the information on the MRO's copy. The staff may resolve errors in custody-and-control forms that require corrective action(s), but shall forward the custody-and-control forms to the MRO for review and approval of the resolution.

(iii) The staff may not conduct interviews with donors to discuss positive, adulterated, substituted, invalid, or dilute test results nor request medical information from a donor. Only the MRO may request and review medical information related to a positive, adulterated, substituted, or invalid test result or other matter from a donor.

(iv) Staff may not report nor discuss with any individuals other than the MRO and other MRO staff any positive, adulterated, substituted, invalid, or dilute test results received from the HHS-certified laboratory before those results have been reviewed and confirmed by the MRO. Any MRO staff discussions of confirmed positive, adulterated, substituted, invalid, or dilute test results must be limited to discussions only with the licensee's or other entity's FFD program personnel and may not reveal quantitative test results or any personal medical information about the donor that the MRO may have obtained in the course of reviewing confirmatory test results from the HHS-certified laboratory.

§ 26.185 Determining a fitness-for-duty policy violation.

(a) *MRO review required.* A positive, adulterated, substituted, dilute, or invalid drug test result does not automatically identify an individual as having used drugs in violation of the NRC's regulations, or the licensee's or other entity's FFD policy, or as having attempted to subvert the testing process. An individual who has a detailed knowledge of possible alternate medical explanations is essential to the review of the results. The MRO shall review all positive, adulterated, substituted, and invalid test results from the HHS-certified laboratory to determine whether the donor has violated the FFD policy before reporting the results to the licensee's or other entity's designated representative.

(b) *Reporting of initial test results prohibited.* Neither the MRO nor MRO staff may report positive, adulterated, substituted, dilute, or invalid initial test results that are received from the HHS-certified laboratory to the licensee or other entity.

(c) *Discussion with the donor.* Before determining that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation and reporting it to the licensee or other entity, the MRO shall give the donor an opportunity to discuss the test result or other occurrence with the MRO, except as described in paragraph (d) of this section. After this discussion, if the MRO determines that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation, the MRO shall immediately notify the licensee's or other entity's designated representative.

(d) *Donor unavailability.* The MRO may determine that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation without having discussed the test result or other occurrence directly with the donor in the following three circumstances:

(1) The MRO has made and documented contact with the donor and the donor expressly declined the opportunity to discuss the test result or other occurrence that may constitute an FFD policy violation;